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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/781,589	02/17/2004	Karel F.A. Smits	P-7718.04	3425

27581 7590 07/27/2005

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EXAMINER	
MULLEN, KRISTEN DROESCH	
ART UNIT	**PAPER NUMBER**
3762	

DATE MAILED: 07/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/781,589	SMITS, KAREL F.A.	
	Examiner	Art Unit	
	Kristen Mullen	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,13 and 14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,13,14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 February 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Abstract

1. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. *It should avoid using phrases which can be implied,* such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Claim Objections

2. Claim 1 is objected to because of the following informalities: a typographical error exists in section c where it is recited that "the electrical connector being contiguous with the ***distal*** section". Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Swoyer (5,683,445). Swoyer shows an elongated implantable medical electrical lead comprising a lead body having

proximal and distal sections, at least one electrode (15, 20) for sensing or electrically stimulating the heart, a proximal end comprising an electrical connector (2), the connector being contiguous with the proximal end of the lead body, a distal end connected to the distal section of the lead body, at least one electrical conductor having proximal and distal ends, the distal end operatively connected to the at least one electrode and the proximal end being connected to the electrical connector, the distal section of the lead body comprises at least first (51) and second segments (53), the first segment having a bending stiffness S_{bs} greater than the bending stiffness S_{bf} of the second segment, first and second segment configured and dimensioned to impart a distally directed force to the distal end of the lead when the first and second segments are subjected to a bending moment resulting in a sufficient curvature of the distal section of the lead body (Fig. 1).

Assuming arguendo that the first and second segments of the Swoyer lead are not configured and characterized such that a distally directed force is imparted to the distal end of the lead when the first and second segments are subjected to a bending moment resulting in sufficient curvature of the lead body, the bending moment provided by an external force applied to the lead, the examiner points out that second segment (53) is sufficiently flexible to be straightened when located inside a guide catheter (Fig. 6) and first segment is sufficiently stiff when located inside a guide catheter (Col. 4, lines 26-30), thus the second segment would be sufficiently flexible to allow further bending upon application of bending moment and the first segment would be sufficiently stiff to impart a distally directed force upon application of bending moment.

5. Claims 1, 13 and 14 are rejected under 35 U.S.C. 102(e) as being anticipated by Rutten et al. (6,278,897).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

With respect to claim 1, Rutten shows an elongated implantable medical electrical lead comprising a lead body having proximal and distal sections, at least one electrode (128) for sensing or electrically stimulating the heart, a proximal end comprising an electrical connector, the connector being contiguous with the proximal end of the lead body, a distal end connected to the distal section of the lead body, at least one electrical conductor having proximal and distal ends, the distal end operatively connected to the at least one electrode and the proximal end being connected to the electrical connector, the distal section of the lead body comprises at least first (1210) and second segments (125), the first segment having a bending stiffness S_{bs} greater than the bending stiffness S_{bf} of the second segment, first and second segment configured and dimensioned to impart a distally directed force to the distal end of the lead when the first and second segments are subjected to a bending moment resulting in a sufficient curvature of the distal section of the lead body (Fig. 6A).

Regarding claim 13, Rutten shows the distal section of the lead body comprises a third segment (124) having a bending stiffness which exceeds the bending stiffness of the second

segment (125), the second segment being disposed between the first (1210) and third segments (124).

With respect to claim 14, Rutten shows the distal section of the lead body comprises a third segment (122) having a bending stiffness that is less than the bending stiffness of the first segment (1210), the first segment being disposed between the second (125) and third segments (122).

Double Patenting

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claim 1 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 10 of U.S. Patent No. 6,549,812 and claim 1 of U.S. Patent No. 6,718,211. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the present application are broader and are met by the narrower patent claims (the patent claims contain all the limitations of the present application claims).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen Mullen whose telephone number is (571) 272-4944. The examiner can normally be reached on M-F, 10:30 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kristen Mullen

Robert E. Pezzuto
Supervisory Patent Examiner
Art Unit 3762

kdm